DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-726/S-015 and S-016 **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation
Attention: Vincent De Stefano
Drug Regulatory Affairs
One Health Plaza
East Hanover, N.J., 07936-1080

Dear Mr. De Stefano:

Please refer to your supplemental new drug applications dated August 14, 2009, received August 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Femara (letrozole) 2.5 mg Tablets.

We acknowledge receipt of your submissions dated August 14, 2009 and February 5, 2010.

Your submission of August 14, 2009 constituted a complete response to our February 12, 2008 action letters.

S-015 provides for additional clinical data regarding distant disease-free survival with the use of Femara (letrozole) tablets for the indication of adjuvant treatment of postmenopausal, hormone receptor positive, early breast cancer approved under accelerated approval, Subpart H, on December 28, 2005 (S-012).

S-016 provides for a label update to include longer term safety and efficacy data with the use of Femara® (letrozole) tablets for the indication of extended adjuvant treatment of early breast cancer in post-menopausal women after five years of adjuvant tamoxifen approved under accelerated approval, Subpart H, on October 29, 2004 (S-011).

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

These supplements also include a request for full approval of these indications approved on October 29, 2004 (S-011) and December 28, 2005 (S-012) under 21 CFR 314.500 (Subpart H). S-020 was submitted on June 30, 2009, has a user fee goal date of May 1, 2010 and is still under review. A determination of conversion from accelerated approval to full approval will be made by May 1, 2010.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed agreed upon labeling (text for the package insert) submitted February 12, 2010. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-726/S-015 & S-016**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alice Kacuba, Chief, Project Management Staff at (301) 796-1381.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20726	SUPPL-16	NOVARTIS PHARMACEUTICALS CORP	FEMARA
NDA-20726	SUPPL-15	NOVARTIS PHARMACEUTICALS CORP	FEMARA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ALICE KACUBA
03/02/2010

ROBERT L JUSTICE
03/02/2010